Pharmacy Benefit News

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Specialty Spotlight

How To Reduce Inappropriate Antibiotic Prescriptions? Try Behavior Modification!

Behavioral interventions such as accountable justification and peer comparison can help to lower rates of inappropriate antibiotic prescribing for acute respiratory tract infections, according to new research. The study looked at 248 clinicians in 47 primary care practices in Boston and Los Angeles, randomizing them to receive up to three interventions for 18 months. At enrollment, all of the clinicians received guidance on antibiotic prescribing practices. The three behavioral interventions were "suggested alternatives," which presented electronic order sets suggesting nonantibiotic treatments; "accountable justification," which prompted clinicians to enter free-text justifications for prescribing antibiotics into patients' electronic health records; and "peer comparison," which sent emails to clinicians that compared their antibiotic prescribing rates with those of "top performers." According to the data, mean antibiotic prescribing rates dropped from 24.1% at intervention state to 13.1% at intervention month 18 for control practices, from 22.1% to 6.1% for suggested alternatives, from 23.2% to 5.2% for accountable justification, and from 19.9% to 3.7% for peer comparison.

The researchers report, "We found that 2 socially motivated interventions—accountable justification and peer comparison—resulted in statistically significant reductions in inappropriate antibiotic prescribing, while suggested alternatives, which lacked a social component, had no statistically significant effect." An editorial accompanying the study notes that "this report highlights the promise of various types of immediate feedback to improve antibiotic prescribing and justifies further investigation to devise the most effective, generalizable, and sustainable interventions. This might require tailoring the intervention to specific practice, practitioner, or patient characteristics.

Journal of the American Medical Association (02/09/16) Vol. 315, No. 6, P. 562 Meeker, Daniella; Linder, Jeffrey A.; Fox, Craig R.; et al.

COMMENT:
Pro Pharma has had extensive experience in modifying prescriber behavior over more than a decade in each instance. The study above showed that no one wants to be a big bar when their peers are a small bar, comparatively speaking. Further, interventions must be frequent, incorporated into prescriber practices and be based on clinical objections rather than on saving money. No one likes to be told that they are not doing their best, so these programs require the prescribers to go through something similar to Kuler Ross' 5 Stages of Grief. We previously wrote about our experiences in several peer-reviewed articles, which can be accessed below:

Read Article

Find out more

FDA Rejects Expanded Use of Ivacaftor in Patients With Specific Mutations

The Food and Drug Administration (FDA) has denied the expanded use of Ivacaftor (Kalydeco), a Vertex drug, already approved for cystic fibrosis, in patients with specific genetic mutations. The rejection applied to expanding use of the drug in cystic fibrosis patients aged 2 years or older, who have one of 23 residual function mutations. Vertex said its application "was made with limited data" because of the difficulty of including patients with many different genetic mutations in a single clinical study.

The company also included the experience of the patients who have taken Ivacaftor since it was approved 4 years ago. It also submitted preclinical data showing the drug was effective in synthetically created cells harboring different mutations, some of which affect only small numbers of people in the United States.

Boston Globe (02/06/16) Weisman, Robert

Commentary
This issue is going to be more common as medications are targeted to specific genomic mutations in rare diseases/conditions. Obviously, the task of providing data for each, or groups of mutations, in rare conditions is a challenge. The FDA has a comparable problem in identifying criteria for these studies. In addition, does the FDA allow criteria for approval including preclinical data from studies before the medications are tested in humans, or even in the safety/toxicity/dosing studies? It is currently not common for the FDA to accept the effectiveness of a drug based on such preclinical data. However, with the ability to identify genetic mutations (i.e., alleles) will require the FDA to develop new criteria.

There is no surprise that manufacturers will want to expand the use of their medications to larger populations. The problem is in defining those populations, and the effectiveness/safety of the medications developed to treat them. Patients want treatments for rare and complicated diseases with horrible consequences. The new challenge is to define what effectiveness and safety are for these gene targeted agents.

The FDA Takes a New Approach to Opiates

The Deputy Commissioner for Medical Products and Tobacco Robert Califf, MD, notes that more Americans now die every year from drug overdoses than they do in motor vehicle crashes. Opioids were involved in 28,648 deaths in 2014, according to the CDC. The FDA is "announcing a change in course in how our agency approaches opioids — their approval, their labeling, and their prescribing," says Califf. "We are going to fundamentally reexamine the risk-benefit paradigm for opioids and ensure that we consider their wider public health effects." FDA will now convene an expert advisory committee before approving any new drug application for an opioid that is not in an abuse-deterrent formulation. "We're going to improve our communication with the medical community about these drugs," adds Califf. "That starts with enhancing safety labeling. Our goal is to provide better information to doctors about the risks of these drugs and how to safely prescribe them. We're developing changes to immediate-release opioid labeling that will bring it more in line with the extended-release/long-acting labeling that occurred in 2013." After reviewing the existing requirements and hearing recommendations from an advisory committee, the agency will also update its Risk Evaluation and Mitigation Strategy (REMS) program requirements for opioids. "We need to increase the number of prescribers who receive training on pain management and improve the safe prescribing of opioids to decrease inappropriate prescribing," concludes Califf.

FDA Voice blog (02/05/16) Califf, Robert

Commentary
The media interest as well as official oversight of opiate use is a long time coming. We can expect different stakeholders to plead their argument. For example, the American Society for Clinical Oncology has recently requested that cancer patients be exempted from regulations restricting access to opiates. The real issue is for the FDA and healthcare professionals to define the population at risk for opiate abuse. The population to be targeted by regulatory restrictions has long been known as the patients requiring treatment for chronic non-malignant pain.

Patients requiring treatment for end-of-life and for palliative care (patients with serious illnesses requiring relief from symptoms) have also argued for exemption, but ASCO and the American Cancer Society have argued against these exemptions. The

bottom-line is that this is a problem that we created, and must now solve. Health care professionals will have to live with the FDA, CDC and other groups who will act in the absence of health care provider control over inappropriate prescribing practices.

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